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SUBJECT: TAIWAN TIFA FOLLOW UP - PHARMACEUTICALS IN FLUX

REF: A. TAIPEI 2947

¶B. TAIPEI 2570

Summary

¶1. (U) Please see action request in paragraph 14. Over the past five months the U.S. and Taiwan have held three sets of consultations in an effort to resolve differences over pharmaceutical pricing policies. In May, Taiwan agreed to a three-month delay in announcing mandatory price cuts and made several changes to the Fifth Price Volume Survey, which determines the price cuts. Following a Digital Video Conference on September 13, the price cuts have once again been delayed. During the DVC, Taiwan agreed to the U.S. proposal to establish working groups to resolve long term issues like actual transaction pricing, but was unwilling to adopt the Merck 1982 Index for setting patent term for pricing purposes, and pleaded for more time to implement standard contracts. Taiwan confirmed it will not/not use therapeutic groupings for this round of price cuts but may be considering it for the future. U.S. firms continue to argue strongly against generic groupings. Taiwan has requested further training and exchanges and stressed its goal of "creating a fair trading environment" as well as its desire to attract foreign investment in its pharmaceutical and biotech sectors. End Summary.

Pharmaceutical DVC

¶2. (U) As a follow-up to TIFA Talks in May and August, officials from the Department of Health (DOH) and the Bureau of National Health Insurance (BNHI) and USTR and Washington agencies, met via digital video conference on September 13, Taiwan time. The DVC previewed the upcoming announcement of the Fifth Price Volume Survey results scheduled for September 15, now delayed, and reviewed progress on other long-term issues. Taipei officials were led by Vice Minister of Health Mr. Chen Shih-chung and President of the Bureau of National Health Insurance Dr. Liu Chien-hsiang. They were joined by staff,

officials from the Ministry of Economic Affairs, and AIT Econ and Commercial officers. From Washington, the DVC was led by Deputy Assistant U.S. Trade Representative Eric Altbach. He was joined by Tom Bollyky, USTR Asia Pacific and Pharmaceutical Policy, Jeff Dutton, Director for Korea and Taiwan, Department of Commerce, Sue Bremner, EAP/TC, and Rick Ruzicka, AIT/W. The meeting lasted for about 2 hours and covered issues relating to: standard contracts for drug transactions, C survey and data accuracy, use of Merck Index 1982 vs. 1983, therapeutic groupings, and the Price Volume Survey (PVS) implementation date. In addition, DAUSTR proposed that working groups be established to make progress on issues of long-term concern. The following paragraphs highlight the key issues raised in the DVC as well as follow-up conversations over the last several days AIT has had with BNHI/DOH and industry.

Standard Contracts

¶3. (U) DAUSTR Altbach pressed for the introduction of a standard contract for transactions between hospitals and drug distributors before price cuts from the new PVS take affect. Altbach stated that there was a strong case that the immediate implementation of a standard contract would improve accuracy and transparency of data reporting for future price volume surveys and would reduce the black hole. BNHI President Liu stated that he is already working with Taiwan's Fair Trade Commission on this project, but because it is an interagency process and because hospitals and drug firms need to be consulted, it would not be possible to implement so quickly. Vice Premier Chen also noted that DOH was working on other measures as well to improve the trading environment. (Note: After the DVC DOH provided AIT with a copy of new guidelines for doctors when accepting gifts and conference invitations from drug companies. While a step in the right direction, it does not appear to go to the heart of the problem, primarily bulk hospital purchases. End note.)

C Survey and Data Accuracy

¶4. (U) DAUSTR asked for an update on the C Survey, in which BNHI has requested detailed information on 252 transactions where major discrepancies were found between data reported by drug vendors and hospital buyers. Dr. Liu reported BNHI expected to take an additional month to review the data. If BNHI judged that the discrepancy was made in error, then the relevant drug price would be adjusted and no further action would be taken. If BNHI suspected fraud, however, the case would be referred to the Ministry of Justice for appropriate action. USTR's Bollyky reiterated USG points that were raised in August - namely that we would like additional information on whether companies or their employees possibly would be subjected to administrative or judicial penalties and what these penalties might be. BNHI is in the process of providing this information.

Merck Index 1982 vs. 1983 vs. 1984

¶5. (U) As he argued during his August visit, DAUSTR Altbach again stated that for the Fifth PVS it would be most appropriate to use Merck Index 1982 to establish patent term for pricing purposes. BNHI pushed back and stated that contrary to their original plan to use Merck Index 1984, they had already compromised on Merck Index 1983. Based on information provided by BNHI after the DVC, here is an explanation of how the Merck Index has been used in prior surveys:

--The last full PVS (meaning survey of all drugs available in Taiwan's market as opposed to a selected subset of available drugs) was the third PVS, conducted from May 2002 to January 2003. It used transaction data from second and third quarter 2001, and price cuts were implemented March 2003. Merck Index 1980 was used to establish patent term for pricing purposes for the third PVS.

--The Fourth PVS was conducted from January 2004 to July 2005. It used transaction data from second and third quarter 2003 and price cuts were implemented in September 2005. BNHI does not consider this a full PVS, but simply an update or mini-survey of 841 items (about 40% of the market, by value) which appeared to have been improperly priced in the Third PVS. Based on this review, 564 drug prices were adjusted. Because it was an update, no new Merck Index was used.

--The current Fifth PVS was conducted from December 2005 to May 2006. It used transaction data from third and fourth quarter 2004. Price cuts were to have been implemented July 1, initially delayed to October 1, now delayed further. Originally BNHI planned to use Merck Index 1984, but stated during the DVC that they planned to use Merck Index 1983.

¶6. (U) BNHI argues that Merck Index 1983 is the most appropriate for the current PVS because the last complete PVS was conducted three years ago and based patent term on Merck Index 1980. Therefore, now three years after the most recent full survey, it is appropriate to shift the index by three years. In a meeting with Econoff after the DVC, DOH advised that they wanted to move toward a 20-year TRIPS patent protection period. Even if BNHI uses Merck Index 1983, the period would be well in excess of the 20-year TRIPS requirement. Industry has argued, however, that since Merck Index 1980 was also used in the Fourth PVS that a two-year shift to Merck Index 1982 is appropriate.

Therapeutic Groupings

¶7. (U) As a result of information supplied by a PhRMA member company, DAUSTR asked if BNHI was holding to its earlier commitment to eschew therapeutic groupings for pricing purposes. BNHI staff stated that the case in question was a new drug pricing case that had nothing to do with the PVS, and was being appealed by the drug company. It was the case of a newly-patented combination drug, where the expert panel charged with setting a new drug price suggested pricing the drug in comparison with one of the drug's active ingredients already on the Taiwan market. Altbach pointed out that this seemed in effect to be therapeutic grouping and asked for details on the appeal and the outcome of the case. BNHI agreed to provide additional information. BNHI confirmed that therapeutic grouping would not be used in the current PVS, but pointedly would make no commitments about the future, noting that Australia and Italy are using therapeutic grouping in setting drug prices.

¶8. (U) BNHI later provided AIT with additional information about this and another similar case. In both cases the pricing panel, an independent group of experts, suggested that the pricing of these new drugs be based in part on other drugs already in the market. The new drugs would also face any future PVS price cut for drugs in the reference group. Although this is the first time the panel has introduced this concept, BNHI stressed that they were individual cases, and that they do not signal any policy shift. Nonetheless, if these individual cases became the norm, new drug prices would be set in part by therapeutic grouping. Both companies are appealing these decisions. AIT

has expressed interest in these cases and will monitor the cases and their appeals.

Working Groups for Long Term Issues

¶9. (U) DAUSTR mentioned that during the May TIFA Talks, BNHI suggested establishing working groups to push progress on long-term issues. Altbach suggested that this would be a good structure to continue dialogue on these items, specifically suggesting working groups for:

--Separating prescribing and dispensing (SPD),

--Developing a standard contract and transparent, accurate data gathering, and a fair trading environment, and

--Actual transaction pricing (ATP).

Dr. Liu endorsed this idea. Altbach stated that he would provide suggestions on how to structure these working groups to move forward.

Taiwan's Intended Deliverables

¶10. (U) At the DVC and in follow-up conversations with AIT, Dr. Liu and BNHI staff enumerated a list of concrete decisions that BNHI has taken as a result of the TIFA consultations with AIT, USTR and industry. They are listed below along with BNHI's estimate of how much each action saves the pharmaceutical industry. These numbers are estimates only and reflect savings that accrue to all drug firms, not just American firms.

--The effective date for the new reimbursement schedule (i.e. price cuts) was postponed from July 1 to October 1 (now further delayed). BNHI stated that this change will reduce the impact of price cuts on pharmaceutical firms by NT$2-3 billion (approximately US$61-92 million).

--The R-zone was expanded to 15% from 2%, which was adopted with reference to the Japan system, to encourage new drugs to enter the Taiwan market. This reduces the impact of price cuts by NT$2 billion (approximately US$61 million).

--Angio-tension receptor blocker (ARB) drugs will not be subject to groupings, but will be reclassified as patented drugs for related adjustments - a change that will benefit 15 innovative drugs of six companies, reducing the impact by NT$390 (approximately US$12 million)

--Nineteen categories of drugs, including EPO and insulin, on which the original R&D companies maintain competitiveness, will not be subject to price adjustments. This will influence the prices of 188 drugs of 16 companies, reducing the cost impact of the price cuts by NT$790 million (approximately US$24 million).

--The patent year is changed to 1983 from the previously announced 1984. With one more year of patent protection, this affects 33 drugs of 11 companies, reducing the impact by NT$400 million (approximately US$12 million)

No Talk of Generic Grouping

¶11. (U) U.S. and other foreign firms here in Taiwan have expressed their concern that generic grouping has not been raised as part of our bilateral discussions. They have argued strongly to BNHI that generic groupings inflate the price of generic drugs, many of which have not been tested for biological equivalence and are not

manufactured under quality control regimes that match those for brand name drugs. In turn, generic grouping reduces the reimbursement price of brand-name off-patent drugs. Industry has pushed for no groupings at all, arguing that it would reduce drug costs for BNHI. Eliminating generic groupings, however, could also harm the bottom line of member hospitals, since they use the larger discounts given by generics to subsidize their overall operations. AIT has advised industry that we will pass on their concerns to USTR and that they should also raise their concerns directly with USTR via their corporate offices or PhRMA.

What Are We Waiting For?

¶12. (SBU) All eyes are now on the Bureau of National Health Insurance which has again postponed announcing the final PVS results and delayed the October 1 implementation date. Although BNHI and the DOH claim all of the decisions have been made, industry tells AIT that BNHI and DOH are bickering over some of the details, possibly over the generic grouping issue. They seem paralyzed by the concern

that the USG has not formally signed off on their changes as part of the consultation process. They fear that the USG might make formal objections to the PVS results similar to objections raised earlier this summer. After consulting with USTR, AIT declined to provide any blanket guarantees, and we advised DOH/BNHI that they are fully aware of USG views on the current PVS and hope that they consider them. We also noted that the USG appreciated the open dialogue that occurred with AIT and industry over the past few months and looked forward to working closely together on long-term issues.

Training and Exchange Requests

¶13. (U) BNHI and DOH have made several general training requests ranging from studying the Orange Book and patent linkage drug pricing for Medicare, learning about independent community pharmacies, and, a new request, auditing hospital administrative costs. AIT is working with BNHI and DOH to clarify these requests and is also working with USTR's Tom Bollyky coordinating these requests with relevant USG agencies.

Next Steps

¶14. (U) Action requests for USTR: 1) We look forward to receiving additional information from USTR on possible training opportunities for DOH/BNHI staff. 2) BNHI is awaiting suggestions from USTR on how the proposed working groups should be constituted and the scope of their work. Please provide AIT guidance on this issue. On our part, AIT is gathering additional information from DOH/BNHI on the C Survey as well as on the individual drug pricing cases raised during the DVC.

¶15. (SBU) Comment: As the Fifth PVS comes to a belabored, dramatic close, it is probably time to declare victory and move forward on the longer term issues. Long term reforms to the health care system discussed under the TIFA process are supported by the government and the health care bureaucracy. Vice Minister Chen noted, in his closing remarks during the DVC, he hoped reforms would help create an environment that would attract foreign biotech and pharmaceutical firms. Nonetheless, the political realities of taking on powerful domestic health care interests, and curbing the excesses in a popular, inexpensive health care system will require our persistent, full, and active engagement.
YOUNG